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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,320	05/14/2001	Robert Bayer	19957-014110	1113

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/27/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,320

Applicant(s)

BAYER, ROBERT

Examiner

Manjunath N Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-6, 9, 11, 12, 15, 20, 21, 54 and 55 is/are allowed.
- 6) ☒ Claim(s) 1, 7, 8, 10, 13, 14, 16-19, 31-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-55 are still at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-21, 33-55 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that coexamination of all of Groups not place an undue burden on the Examiner. This is not found persuasive because two independent inventions which are related as discussed in the previous Office action are presented in claims 1-55 and while the searches for the two groups overlap, they are not coextensive. The search for Groups II would each require the search of subclasses unnecessary for the search of elected Group I. For example, search of Group I would require search of subclass 435/72 and search of Group II would require search of subclass 530/350.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-32 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 32 and claims 33-53 which depend from claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31 and 32 recite the phrase "substantially identical". It is not clear to the Examiner as to what applicants mean by "substantial". The term as such is an "open" term as it is not clear to the Examiner as to how much (in terms of a numerical value) fucosylation is considered by the applicants as "substantial". Therefore, without a numerical value attached to the term "substantial" the above claims are rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 10, 13, 14, 16-19, 31, 40, 42, 45, , 46, 48, 49, 50, 51, are rejected under 35

U.S.C. 102(b) as being anticipated by Wang et al. (Glycobiology, 1996, Vol. 6(8):837-842).

This rejection is based upon the public availability of a printed publication. Claims 1, 8, 10, 13, 14, 16, 17, 18, 19, 31, 40, 42, 45, , 46, 48, 49, 50, 51 of the instant application are drawn to a

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method of fucosylation of a glycopeptide comprising an acceptor moiety comprising contacting the glycopeptide with a reaction mixture containing fucose donor moiety and a fucosyltransferase under appropriate conditions to transfer fucose from the donor to acceptor such that the glycopeptide has a substantially uniform fucosylation pattern, wherein the fucosyltransferase is recombinantly produced, wherein 80% of the acceptor moieties are fucosylated, wherein the glycopeptide is a full length peptide, wherein the glycopeptide is an enzyme, cytokine etc. wherein the glycopeptide is on a cell, wherein the donor is a GDP-fucose. Wang et al. teach an identical method of fucosylating a glycopeptide. The reference does not explicitly report that 80% of the acceptor moieties are fucosylated. At the same time the reference does not also say that less than 80% of the moieties were fucosylated. Therefore, Examiner takes the position that this information is inherent in the reference and that 80% or more of the moieties were fucosylated. Furthermore, since the Office does not have the facilities for examining and comparing applicants' method with the method of the prior art reference, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. Thus Wang et al. anticipate claims 1, 8, 10, 13, 14, 1617, 18, 19, 31, 40, 42, 45, , 46, 48, 49, 50, 51 of this application as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. as applied to claims 1, 8, 10, 13, 14, 1617, 18, 19, 31, 40, 42, 45, , 46, 48, 49, 50, 51 above, and further in view of Ge Wang et al. (Microbiology, 1999, Vol. 145:3245-3253). Claims 7 and 39 are drawn to a method of fucosylation of a glycopeptide comprising an acceptor moiety comprising contacting the glycopeptide with a reaction mixture containing fucose donor moiety and a fucosyltransferase under appropriate conditions to transfer fucose from the donor to acceptor such that the glycopeptide has a substantially uniform fucosylation pattern, wherein the fucosyltransferase is recombinantly produced, wherein 80% of the acceptor moieties are fucosylated; wherein the glycopeptide is a full length peptide, wherein the glycopeptide is an enzyme, cytokine etc. wherein the glycopeptide is on a cell, wherein the donor is a GDP-fucose and wherein the fucosyltransferase is from a bacteria.

Ge Wang et al. teach a fucosyltransferase from a bacteria, *Helicobacter pylori*. However, the reference does not teach the above method.

The reference of Wang et al. as it applies to claims 1, 8, 10, 13, 14, 1617, 18, 19, 31, 40, 42, 45, 46, 48, 49, 50, 51 has been discussed above. With a new bacterial enzyme available from Ge Wang et al. it would have been obvious to one of ordinary skill in the art to use the bacterial enzyme in place of the enzyme taught by Wang et al. One of ordinary skill in the art would have

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been motivated to do so in order to find out whether the new enzyme can be used to replace the enzyme taught by Wang et al. One of ordinary skill in the art would have a reasonable expectation of success as Wang et al. teach the fucosylation method and Ge Wang et al. provide a bacterial enzyme.

Therefore, the above would have been rendered *prima facie* obvious to one of ordinary skill in the art.

Conclusion


Claims 2-6, 9, 12, 15, 20-21 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao, Ph.D.
September 24, 2002


MANJUNATH RAO
PATENT EXAMINER